

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ophthalmic Devices Panel of the Medical Devices Advisory Committee;

Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 5, 2004, from 9 a.m. to 5 p.m., and February 6, 2004, from 8 a.m. to 4:30 p.m.

Location: Gaithersburg Marriott, Salons A, B, C, and D, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2053, ext. 127, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512396. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 5, 2004, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for a phakic intraocular lens for the reduction or elimination of myopia in adults.

On February 6, 2004, the committee will discuss, make recommendations and vote on a PMA for a radiofrequency electrosurgical corneal shaping device for the temporary treatment of presbyopia. Background information for each day's topic, including the attendee list, agenda, and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. Material for the February 5, 2004, session will be posted on February 4, 2004; material for the February 6, 2004, session will be posted on February 5, 2004.

Procedure: On February 5, 2004, from 9 a.m. to 5 p.m., and on February 6, 2004, from 9:30 a.m. to 4:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 26, 2004. On February 5, 2004, formal oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m. Near the end of the committee deliberations on the PMA, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. On February 6, 2004, oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m. Near the end of committee deliberations on the PMA, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before

January 26, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On February 6, 2004, from 8 a.m. to 9:30 a.m., the meeting will be closed to permit FDA staff to present to the committee trade secret and/or confidential commercial information relevant to pending and future device submissions for vitreoretinal, surgical and diagnostic devices, intraocular and corneal implants, and contact lenses. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 301-594-1283, ext. 113, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act
(5 U.S.C. app. 2).

Dated: January 5, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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